



11 Publication number:

0 651 968 A1

(12)

## **EUROPEAN PATENT APPLICATION**

2) Application number: 95200028.9

(5) Int. Cl.6: A61B 5/00

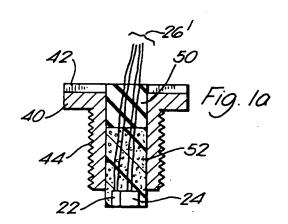
② Date of filing: 16.08.90

This application was filed on 09 - 01 - 1995 as a divisional application to the application mentioned under INID code 60.

- ® Priority: 17.08.89 US 394997
- 43 Date of publication of application: 10.05.95 Bulletin 95/19
- Publication number of the earlier application in accordance with Art.76 EPC: 0 413 588
- Designated Contracting States:
   AT BE CH DE DK ES FR GB IT LI LU NL SE

- Applicant: CRITIKON, INC. 4110 George Road Tampa Florida 33634 (US)
- Inventor: Tan, Josef Kie Sloe 3208 Rowan Lane Tampa, Florida 33618 (US)
- Representative: Fisher, Adrian John et al CARPMAELS & RANSFORD
   43 Bloomsbury Square London WC1A 2RA (GB)

- (Market oxygen sensor.
- An epidural oxygen sensor comprises a photodetector (24) and light emitting diodes (22) mounted at the end of a core of compressible foam (52) extending from the end of a hollow bone screw (40). As the bone screw is screwed into a burr hole in the skull, the photodetector and light emitting diodes will contact the dura and the foam will compress to maintain optical contact between the electrical components and the dura. Light from the diode is reflected by blood in the dura and brain, received by the photodetector, and the resultant electrical signals are processed by a pulse oximeter.



The invention relates to sensors for determining the oxygen saturation of tissues within the skull and, in particular, to such sensors which are placed epidurally through the skull to measure oxygen saturation.

1

During neurological and neurologically related surgical procedures it is oftentimes desirable to continuously monitor the oxygenation of blood which is supplied to the brain. Frequently access is gained to the brain through a borehole in the skull, and a sensor which measures oxygenation can then be inserted through such a borehole. A sensor should then exhibit numerous design and performance criteria in order to operate satisfactorily in this environment. The sensor must be capable of insertion through the borehole so as to contact tissue where oxygen saturation is to be measured. The sensor must be soft so that it does not damage neurological tissue, yet be sufficiently rigid in certain dimensions so that it can be maneuvered from outside the skull. It also must be sized to fit inside the borehole and in the location where measurements are to be taken. Furthermore, the sensor must be designed so as to eliminate detection of ambient light which will interfere with detection of the desired optical signals. The sensor must also prevent the detection of directly transmitted light from the light source of the sensor.

In accordance with the principles of the present invention, an optical sensor is provided for epidural measurement of blood oxygenation. The sensor comprises a pair of light emitting diodes (LED's) which emit light at two predetermined wavelengths. The sensor also includes a photodetector for receiving light emitted by the LED's which has been reflected from adjacent blood perfused tissue.

The LED's and photodetector are located in a hollow bone screw, with the components opposing the tissue from which measurements are to be taken. The components are backed by a soft polymer which will compress under gentle pressure as the bone screw is tightened to cause the components to contact the dura.

In the drawings:

Figures 1a to 1c are cross-sectional, top and bottom views of an epidural oxygenation sensor mounted in a hollow bone screw.

Bone screw 40 is threaded as indicated at 44 to screw into the skull, and the head of the screw has a slot 42 to turn the screw with an adjustment instrument as more clearly shown in the top plan view of Figure 1b. A photodetector 24 and a pair of LED's 22 are located at the bottom of a core of soft, compressible foam material 52 in the centre of the screw, as shown in the bottom plan view of Figure 1c. Above the compressible foam 52 the centre of the screw is filled with a firm filling 50 of silicone rubber or polyurethane. The electrical

leads 26' from the LED's and photodetector pass through the foam material 52 and the filling 50 and exit through the top of the hollow screw as shown in Figure 1c.

In use of the sensor of Figures 1a to 1c, a hole is drilled in the skull into which the bone screw 40 is screwed. As the bone screw is screwed into the skull, the oximeter monitor is continuously monitored for the onset of oxygen saturation readings. When the bottom of the screw with the sensor components contacts the dura, oxygen readings will commence, and will initially occur erratically. As the bone screw is slowly turned the sensor components will make better contact with the dura and the signal quality will improve. The contact between the sensor components and the dura is induced in a gentle manner by the compressible foam 52, which will readily compress as the components make contact with the dura to prevent damage to the dura. When consistent readings occur no further turning of the screw is necessary, as the sensor components are in good surface contact with the dura and will gently ride on the dura due to the compressibility of the foam 52. This hollow bone screw embodiment is desirable for its ability to completely block ambient light from the sensor components and by plugging the burr hole with the bone screw infection of the dura is retarded. The sensor can be safely left in place in the burr hole for extended periods of time.

## Claims

30

35

40

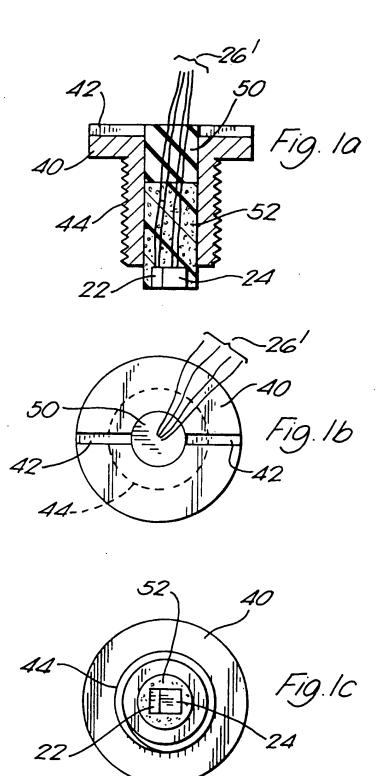
- A sensor for measuring cerebral oxygen saturation through a burr hole in the skull by optical reflectance comprising:
  - a hollow bone screw (40);
  - a core of compressive material (52) located in said hollow bone screw and having an upper surface oriented toward the top of said bone screw and a lower surface oriented toward the bottom of said bone screw; and
  - a photodetector (24) and a pair of light emitting diodes (22) located at said lower surface of said core of compressive material, wherein electrical connection is made to said photodetector and said light emitting diodes through said hollow bone screw.
- The sensor of claim 1, further comprising a core of relatively less compressive material (50) located within said bone screw (40) above said upper surface of said compressive core (52).
- The sensor of claim 1 or claim 2, wherein a portion of said core of compressive material (52) extends out from the lower end of said

55

EP 0 651 9

EP 0 651 968 A1

hollow bone screw (40).





RPO PORM 1503 03.82 (POICOL)

## **EUROPEAN SEARCH REPORT**

Application Number EP 95 20 0028

|   |   | IDERED TO BE RELEVAN  | T   | <del> </del>                                   |
|---|---|---|---|--|
| Category  | Citation of document with of relevant p   | Indication, where appropriate,  | Relevant<br>to claim  | CLASSIFICATION OF THE<br>APPLICATION (Int.CL5) |
| P,X   | WO-A-90 07907 (NEU<br>* page 8, line 13<br>figures 6-8 *  | RODYNAMICS INC)<br>- page 9, line 15;   | 1   | A61B5/00                                       |
| A   | EP-A-0 248 103 (HEI<br>* the whole document   |   | 1-3   |  |
| A   | US-A-4 328 813 (RA'<br>* the whole docume   | ( C D)  | 1-3   |  |
| A   | US-A-4 646 752 (SW/<br>* the whole docume   | ANN K W ET AL)  | 1   |  |
| A   | NO. 2, PAGES 98 - 3<br>Schmitt J M et al<br>circuit-based option<br>measurement of bloom  | 1986, USA, VOL. BME-33,<br>107, ISSN 0018-9294<br>An integrated<br>tal sensor for in vivo | 1   | ·  |
|   | page 105, left colu<br>figures 5,9 *  | umn, paragraph 2;   |   | TECHNICAL FIELDS<br>SEARCHED (Int.Cl.5)        |
|   |   |   | ·   | A61B   |
|   |   |   |   |  |
|   |   |   |   |  |
|   |   |   |   |  |
|   |   |   |   |  |
|   | The present search report has b   | een drawn up for all claims   |   |  |
|   | Place of search   | Date of completion of the search  | نـــــــــــــــــــــــــــــــــــــ  | Remotaer                                       |
|   | BERLIN  | 13 February 1995  | Joh   | nson, K  |
| X : parti<br>Y : parti<br>docu<br>A : techi<br>O : non- | ATEGORY OF CITED DOCUMES<br>cularly relevant if taken alone<br>cularly relevant if combined with and<br>ment of the same category<br>notogical background<br>written disclosure<br>mediate document | NTS T: theory or principl E: earlier patent doc after the filing da                       | e underlying the<br>sument, but publi<br>ite<br>o the application<br>or other reasons | invention<br>ished on, or                      |